



# EFFECT OF REFERENCE PRICING REFORM ON FINNISH PHARMACEUTICAL MARKET EQUILIBRIA

A theoretical approach

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## Abstract

**Objective:** To assess the impact of the introduction of a reference price system in Finland with a theoretical model. The marginal effect of the reference price reform compared to a regular copayment-regime will be evaluated in terms of changes in prices and market shares for a generic vis-à-vis a branded-drug firm.

**Methods:** Using a vertically differentiated model comprising a duopolistic market of one generic and one brand-name drug firm, and assuming a heterogenous pool of consumers with regard to their product tastes, the impact of the implementation of a reference price system will be scrutinized. In the model the drugs are categorized into three alternating reimbursement classes, which allows to differentiate the magnitude of the regulatory impact for drugs with different out-of-pocket copayment rates.

**Results:** Drug prices are reduced across the board as a consequence of the reference price reform. After the introduction of the pricing reform consumer demand turns in favor of the cheaper drug since the opportunity cost for buying the more expensive branded drug increases. Consequently, the brand-name drug firm adapts to the changing competitive environment with substantial reductions in its prices. Furthermore, the price-reductions are most substantial in the reimbursement category of drugs with the highest rate of reimbursement offered by the public health insurer. The model predicts a negative relationship between the copayment rate and drug prices and a positive relationship between the reimbursement rate and the magnitude of the regulatory impact on price-reductions.

**Conclusion:** The results suggest that the introduction of the Finnish reference price system successfully contains pharmaceutical price levels by stimulating more active price competition between the pharmaceuticals. However, the sign of an increased price competition amongst the existing manufacturers says little about the effects on the overall supply of pharmaceuticals. Moreover, since lower prices can deter further competition, the reference price system can pose a constraint on drug innovation, resulting in lower societal welfare.

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**Keywords** Reference price system, brand-name and generic drugs, optimal pricing strategies

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## Table of Contents

<b>1. Introduction .....</b>	<b>1</b>
<b>2. Economics and price regulation in the pharmaceutical industry: A literature review .....</b>	<b>3</b>
2.1 Rationale for regulation in the pharmaceutical industry.....	3
2.2 Overview of pharmaceutical price regulation in the European Union.....	4
2.3 Empirical evidence on the impact of reference pricing .....	5
2.4 Theoretical models covering reference pricing .....	6
<b>3. Finnish pharmaceutical sector and the reference pricing system .....</b>	<b>8</b>
<b>4. Theoretical model: Stackelberg duopoly.....</b>	<b>9</b>
4.1 Demand in the pharmaceutical market.....	10
4.2 Supply in the pharmaceutical market.....	12
4.3 Price-setting Game .....	13
4.4 Quality Game .....	14
4.5 Reference-price reform .....	15
<b>5. Results and discussion .....</b>	<b>18</b>
5.1 Hypotheses based on the Stackelberg model.....	18
5.2 Case study: The impact of reference pricing and extension of generic substitution on the daily cost of antipsychotic medication in Finland .....	18
<b>6. Conclusion .....</b>	<b>20</b>
<b>References .....</b>	<b>22</b>

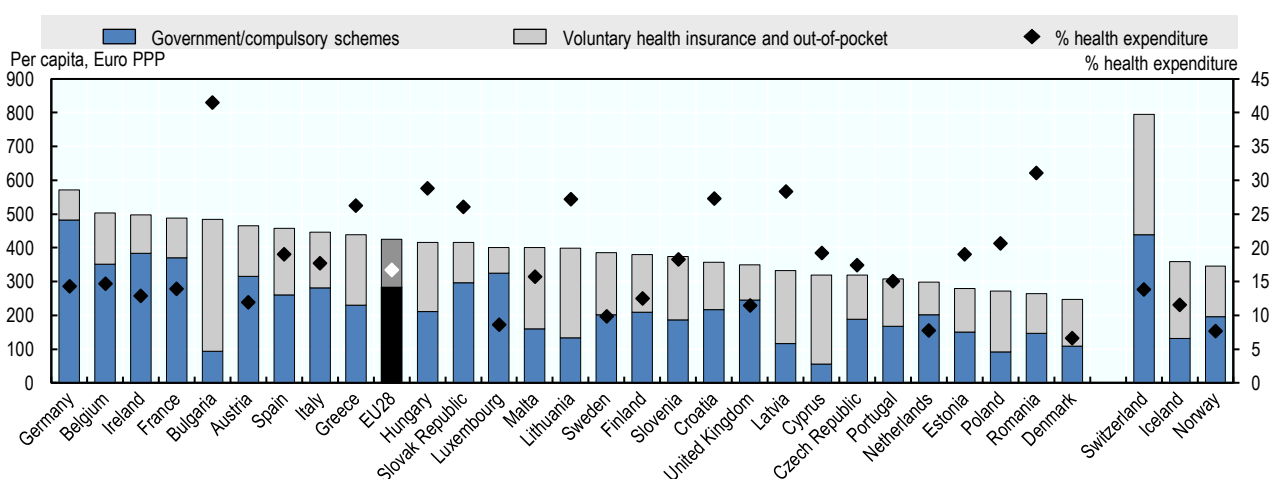
## List of Tables and Figures

TABLE 1. RESULTS COMPARISON .....	15
TABLE 2. EFFECTS OF THE PRICING REFORM .....	17
FIGURE 1. PHARMACEUTICAL EXPENDITURE (RETAIL) PER CAPITA AND AS A SHARE OF HEALTH EXPENDITURE, 2016	1
FIGURE 2. DISTRIBUTION OF DRUG DEMAND BASED ON DEMAND ELASTICITY: AN ILLUSTRATION .....	12

## 1. Introduction

The growth in pharmaceutical expenditures constitutes a prime challenge for containing the development of health expenditures in the EU. After the expenses accounting the management of inpatient and outpatient care, pharmaceuticals sold in the retail sector represent the third largest component of health spending in the Member States (OECD/EU, 2018). Notwithstanding the general trend, regional differences should also be accounted for. For example, whereas pharmaceutical expenditures in Denmark represent just little over 5% of total health spending, Bulgaria measures with more than 40% to her respective share (figure 1). While the level of pharmaceutical spending doesn't necessarily indicate wasteful spending, promoting rational use of drugs by maximizing their value with minimal cost is a critical condition for an efficiently and sustainably performing health care system.

Figure 1. **Pharmaceutical expenditure (retail) per capita and as a share of health expenditure, 2016**



Source: OECD Health Statistics 2018 and Eurostat Database (OECD/EU, 2018)

The presence or lack of competition among pharmaceutical companies in particular therapeutic markets is a pivotal indicator of potential cost-savings available for the health care sector. Patented drugs pave the way for brand-loyalty among consumers, increasing the barriers to entering the therapeutic market for generic firms who take advantage by copying the product characteristics of the original branded drug once the patent has expired. The uptake of generics in therapeutic markets, which comprises medicinal products that are designed to produce similar clinical outcomes, has the potential of reducing the cost of pharmaceuticals and improving the efficiency of drug spending by offering cheaper alternatives to the reference product. The challenges for entering a therapeutic market previously dominated by the patented product can be assisted with a mix of policies, often aimed at to reward the manufacturers capable of offering their drugs with the cheapest prices.

The purpose of this paper is to assess the impact of a pricing reform implemented in Finland in 2009 with a theoretical model. Before the reference price reform of 2009, Finland followed suit with a handful of other Member States by adopting generic substitution in 2003, making pharmacies obliged to inform patients about the cheaper generic alternatives when purchasing

their drug(s). This paper evaluates the marginal effect of the reference price reform compared to a regular copayment-regime in terms of changes in prices and market shares for a generic vis-à-vis a branded-drug firm. While the prevailing contributions to the research on reference pricing have hitherto been mostly empirical, some authors have made their mark in the development of theoretical models in an attempt to better understand the mechanics and outcomes of the policy. For example, in her study of the impact of the reference price system, using a theoretical model, Merino-Castelló (2003) concludes that under the reference price system, brand-name drug producers decrease prices substantially in order to adapt to the new competitive situation while generic prices remain more or less constant. Applying the model developed by Merino-Castelló into the Finnish pharmaceutical sector is in the forefront of this paper. Moreover, while the theoretical foreground for reference pricing schemes has remained on a rather general level - with few attempts that have been made in applying the frameworks into any national regulatory environment, this paper takes on the challenge of evaluating the impact of a reference price system in a specific regulatory environment.

The paper is structured as follows. The first section of the paper reviews literature on the economics and price regulation in the pharmaceutical industry, primarily focusing on European pharmaceutical markets. The literature on pharmaceutical price regulation is reviewed with an emphasis on the empirical as well as the theoretical foundation. The second section introduces the Finnish pharmaceutical sector and the reference price system by presenting the most important institutions and judicial framework covering the national industry. This is followed by the third section which lays out the theoretical model used in the analysis of the impact of the Finnish reference price system. In the fourth section, the main findings of the theoretical model are disseminated. Furthermore, the credibility of the model's predictions will be weighed against a case study that assesses the impact of reference pricing and extension of generic substitution on the daily cost of antipsychotic drugs in Finland. The fifth - and the final section presents a conclusion about the outcomes of this study.

This paper concludes that drug prices will be reduced across the board as a consequence of the reference price reform. After the introduction of the pricing reform consumer demand turns in favor of the cheaper drug since the opportunity cost for buying the more expensive branded drug increases. Consequently, the brand-name drug firm adapts to the changing competitive environment with substantial reductions in its prices. Furthermore, the price-reductions are most substantial in the reimbursement category of drugs with the highest rate of reimbursement offered by the public health insurer. The model used in this study predicts a negative relationship between the copayment rate and drug prices and a positive relationship between the reimbursement rate and the magnitude of the regulatory impact on price-reductions.

## 2. Economics and price regulation in the pharmaceutical industry: A literature review

### 2.1 Rationale for regulation in the pharmaceutical industry

The pharmaceutical markets are endemic of numerous market failures which lead to mismatches between supply and demand if not explicitly or implicitly dealt with. The scope of these market failures provides a crucial reason for why pharmaceutical markets worldwide are so heavily regulated. While the ratio between private and public spending varies across countries, so does the level and nature of regulation inflicted upon market authorization, drug approval, pricing of pharmaceuticals and reimbursement policies. In essence, national health systems are without exceptions immense totalities simultaneously reflecting the effects of national policy objectives, local disease burdens, demographical aspects and the relationship of wealth and health care resources of these nations to their actual health care demand. The net-effect of different country characteristics rarely results in equal choices in the type of regulation used to manage the outflow of pharmaceuticals which constitutes an integral part of the health care system.

While the pharmaceutical markets are crippled by market failures, some of these failures are more benign than others. For example, as one of the prime characteristics of the pharmaceutical industry, intellectual property rights and most crucially patent protection for development and manufacturing of drugs has been widely accepted and implemented as a pertinent tool for sparking drug innovation. On the other hand, in his cross-country empirical study, Qian (2007) finds that national patent protection alone fails to stimulate domestic innovation, and that the positive relationship between patent implementation and innovativeness occurs only in developed countries with high levels of economic freedom and educational attainment. Nevertheless, patent protection of new pharmaceuticals remains deeply ingrained in the industry, providing a reason for instance to price regulation for patented drugs in order to curb excess use of monopoly power of a patent holder and to level the playing field by stimulating generic competition after patent expiration.

While some drugs, most notably prescription drugs that are only accessible by a physician's consent, have been momentarily stripped from competition by having achieved exclusivity from a patent, the demand becomes skewed in favor of these drugs even after their patent has expired because consumers, physicians and pharmacists hesitate to switch to competing products, mainly because of risk-aversion (Carroll & Wolfgang, 1991; Mason & Bearden, 1980). The presence of brand loyalty in the pharmaceutical markets can slow the diffusion of generics after expiration of a patent and can even lead to increasing prices for the branded products. For example, Frank and Salkever (1997) argue that, left to its own devices, the outburst of generic competition leads to increasing prices for branded drugs because the average price sensitivity faced by the branded firm decreases after most price-sensitive consumers have switched to generic products. Ching (2010) hypothesizes that the persistence of price increases by the innovator is due to gradual learning and acceptance of generics but admits also the innovator's incentive to lower its prices in order to slow down this learning process. Because of brand loyalty and potential customer segmentation based on demand elasticity there is a further reason to regulate the pharmaceutical markets.

Yet another cause for pharmaceutical market failure stems from the widespread use of drug insurance. As such, pharmaceutical insurance is likely to cause moral hazard in customers who pay less than the true cost of their drugs. By making consumer demand less price elastic, medical insurance has been estimated to add up to an additional increase in aggregate spending of pharmaceuticals (Danzon & Pauly, 2002). Moreover, Lundin (2000) finds indication of moral hazard in Sweden from the physician's side as well. He finds support that physicians make their prescription decisions on a discretionary basis and before they make their decisions they take into consideration what part of the costs are to be borne by the government and the patient respectively. Since moral hazard is a likely occurrence in the pharmaceutical markets both for patients and for physicians, the rationale for additional regulation is yet again substantiated for mitigating drug costs.

## 2.2 Overview of pharmaceutical price regulation in the European Union

In the European Union pharmaceutical pricing is by and large heavily regulated with a plethora of idiosyncrasies between member states with regard to different methods and scope of regulation used. However, the goals of regulators are often increasingly aligned, and cost-containment of public and private pharmaceutical spending, equitable opportunities for drug consumption and the safety and efficacy of drug authorization and innovation are often found on the list of top priorities for regulatory authorities across Member States. Mrazek (2002) has identified four principle approaches to pharmaceutical price regulation with some methodological differences between EU countries: fixed pricing, cost-effectiveness pricing, profit controls, and reference pricing. In addition to differences in distinctive approaches used, pharmaceutical pricing can be subject to alternating national informal rules and formal regulation depending for example on different types of medicines or different positions in the drug distribution value-chain; e.g. different pricing statutes can exist for pharmacies compared to wholesalers or manufacturers.

Based on Mrazek's (2002) literature survey, the most commonly shared form of price regulation in the EU involves fixed pricing, also known as price-cap regulation, of pharmaceuticals at some level in the value-chain, most commonly covering ex-factory or wholesale prices for publicly reimbursable pharmaceuticals. The idea is to fix pharmaceutical prices to a "reasonable" level, which is often defined with a set of factors indicating the given priorities of the national health care system in question. The priorities can range from prescribing behavior to patterns of utilization, but they can also become subject to case-by-case discretion used by the regulatory authorities if deemed necessary; for example this could happen in cases where the pharmaceutical contains a completely new active substance. A fixed reference price can be determined at a national or international level. For example, countries may consider an average EU price from a basket of comparable products used in other countries. Alternatively, and particularly in cases where the substitute products belonging to an identical therapeutic group are onerous to find in other countries, the reference price can also be defined internally. Fixed pricing provides an incentive for firms to function more efficiently but it can also drain incentives from innovation and the targeting of research and development resources to better quality or more innovative, but pricier products. Another concern is whether competition is revitalized below the maximum price or not, potentially contributing to implicit collusion and a lack of competition between pharmaceutical companies.

Cost-effectiveness pricing is another way of quantifying a “reasonable” price level for pharmaceuticals seeking market authorization from regulatory authorities. This method is often part of the process of determining an appropriate price for a pharmaceutical in terms of the economic value, e.g. cost-savings, it can produce compared to the costs of its utilization for the health care system and to the general public. Countries may or may not define a particular threshold for the value-for-money criterium before a product can be deemed eligible for further regulatory evaluation. In some countries it is required that companies share pharmacoeconomic data on their product, whilst in other countries the manufacturer itself may be liable to demonstrate the reduction in total health care costs compared to competing products.

Profit controls for pharmaceutical companies remains a more exotic form of pricing regulation in the EU. Since 1957, the UK has implemented profit controls for branded pharmaceuticals sold to the National Health Service with the intention to retain the ability to procure reasonably priced medicines simultaneously while encouraging a profitable pharmaceutical industry with the capabilities to remain competitive and innovative in terms of medical development. While the UK’s profit control scheme specifically restricts the level of rate-of-return earned on capital employed of pharmaceutical companies, it can also be argued to discourage cost-containment and operational efficiency since the loss of profitability caused by increased costs can be recouped by increasing prices, which are under no subject to regulation.

The principle of reference pricing schemes on the other hand is to set a reimbursement limit for pharmaceuticals based on a predetermined reference price defined inside a pool of substitutable drugs. Drugs are deemed interchangeable if they seek to produce similar therapeutic effects and clinical outcomes. Consequently, they must reach a certain level of bioequivalence in order to be considered substitutable with each other. In many EU countries the state subsidizes private drug consumption by paying a portion of the drug bill if the drug belongs to the national reimbursement system. However, while the reference price sets a limit for drug reimbursement in a given group of substitutable products, prices above the reference price are not entitled to any reimbursements. Thus, the consumer must pay the difference between the drug price and the reference price wholly out of pocket if the price of the drug exceeds the reference price. Reference pricing encourages physicians and patients to consider the costs of reimbursable medicines in the situation where the patient is prescribed pharmaceuticals. Ultimately, the patient is free to choose whether or not to opt for the wholly reimbursable drug, but at least the reference price gives an incentive to choose the cheapest drug(s). As such, the main objective of reference pricing remains to contain public drug reimbursement costs as well as the out-of-pocket drug costs for consumers.

## 2.3 Empirical evidence on the impact of reference pricing

Reference pricing schemes differ between countries with respect to product coverage, pricing methods and whether or not patented drugs are included in the scheme. As a result, common conclusions may be hard to draw from existing empirical studies about the effect of reference pricing *per se* on price competition, drug consumption and reimbursement costs respectively. Likewise, as regards to the results that may seem indicative of the pricing policies, they must be accounted for their durability as well. Negligence of the long-term impact of the regulation leaves



an incomplete picture of the effects on pharmaceutical costs. Hence, it is desirable to include the long-term effects of the reforms too if applicable.

While individual countries have been put under the spotlight when assessing the effects of reference pricing reforms, Puig-Junoy (2010) has detailed the results of different countries' experiences with pharmaceutical price regulation in the EU. His literature review on dynamic competition in the prices of generic medicines yields some important aspects of both the price-cap regulation as well as reference pricing reforms. For example, based on reports conducted by national health care planners, national and supranational interest groups, the European Commission and individual researchers Puig-Junoy draws the conclusion that price-cap regulation leads to a levelling off of generic prices at a higher level than would occur in the absence of this regulation. This means that the outburst of generic competition does not suffice to result in dynamic price competition but leads to price convergence to the highest regulated price instead.

The shortfall of price competition in a regulatory environment where price-caps exists has imperative consequences to reference pricing schemes as well since the reference price indicates such a cap on prices - albeit to a lesser degree than a *de facto* price-cap. Accordingly, in several countries where the pharmaceutical market comprises reference pricing regulation it is observed that generics fail to lower their prices below the reference price until the insurer lowers its maximum reimbursement rate (Puig-Junoy, 2010). Another phenomenon illuminating the friction in price competition is the renouncement of generic entries. For example, Moreno-Torres et al. (2009) observe in the Spanish pharmaceutical market that besides the number of existing generic entrants, the main factor slowing down generic entry is the reference pricing system itself, as it deprives generic drugs of their main advantage vis-à-vis brand-name equivalents, namely a considerably lower price. In effect, one could hypothesize that the abstinence of potential new generic entries in the market does not lead to an optimal amount of competitors in order to fully economize the price reductions by the health care system.

Despite the shortcomings of reference pricing systems, strong evidence remains about their ability to reduce drug prices (Puig-Junoy, 2010). Moreover, the impact on price reduction seems to be greater for originator-branded pharmaceuticals than for generics. Furthermore, the negative impact of reference pricing on drug prices is greater when compulsory generic substitution exists and with frequent adjustment of the maximum reimbursement rate than with differential co-payments or the adoption of the lowest price as a reference (European Commission, 2009; Puig-Junoy, 2010). Beyond price reductions at the consumer level, pharmacies are observed to receive large discounts from the pharmaceuticals they purchase in countries where maximum reimbursement limits, such as reference pricing exists. While the extent, transparency and legality of pharmaceutical discounts given to pharmacies varies, the effects of reference pricing and other pricing reforms in different countries must be assessed with increased discretion.

## 2.4 Theoretical models covering reference pricing

Prevailing contributions to the research on reference pricing have hitherto been mostly empirical. Nevertheless, some authors have made their mark in the development of theoretical models in an attempt to better understand the mechanics and outcomes of the policy. Based on the selected theoretical frameworks, the effects of enforcing a maximum reimbursement limit on drug costs

can result in multifaceted outcomes with respect to drug prices, aggregate medical spending, market coverage, quality of products and health outcomes. Moreover, the effects of the pricing policy seem to be highly dependent of the definition and scope of the reference price as well as the reference price group. Furthermore, the ambiguity of the effects owes to the assumptions made about the intensity of barriers to market entry as well as patient behavior.

Using a horizontally differentiated duopoly model where a branded-drug and a generic drug firm compete *à la Bertrand*, Mestre-Ferrandiz (2003) compares a reference pricing system implemented in Spain with a copayment-regime where consumers only pay a fixed proportion of their whole drug bill at any case. The model indicates that setting up a reference price system leads to reduced prices for both brand-name and generic pharmaceuticals and reduced pharmaceutical spending only if the reference price is set within a certain interval. In addition, compared to a copayment-regime, total demand of pharmaceuticals is higher under the reference price system even though the demand for generic drugs is actually lower. The loss of demand from the generic's side is more than compensated from an increased demand facing the branded drug. Furthermore, the profits of the generic producer are unambiguously reduced if the reference price is set anywhere in this interval. With regards to the health insurer, in case of a higher reference price it would be more costly to finance branded drugs but cheaper to finance generics. However, as long as the reference price doesn't exceed a given interval the insurer bears lower cost-burden compared to a copayment-regime.

Merino-Castelló (2003) inspects a vertically differentiated duopoly of a branded and a generic drug producer in a market where consumers are differentiated from each other according to their tastes for the respective drugs. The differing consumer tastes are representative of differences in price elasticities since a patient with a higher taste faces higher reluctance to switch to cheaper generics from a branded drug. Furthermore, the branded drug is perceived to consist of higher quality than the generic drug because of its brand-value. In light of the model, the author analyzes the effects of reference pricing in situations where the generic producer enters the market after patent expiry, and simultaneously with the branded drug. Additionally, both situations are analyzed using Bertrand as well as Stackelberg competition respectively, thus, leading to four alternating scenarios with different interpretations. The study concludes that under the reference price system branded producers decrease prices substantially in order to adapt to the new competitive situation while generic prices remain more or less constant. In the models where both producers act simultaneously, market shares do not change after the introduction of reference pricing, whereas when the actions are made sequentially the market share of the branded-drug firm increases as it compensates for reduced profits by selling greater quantities rather than charging higher prices.

Miraldo (2007) studies the effects of a reference price system on firms' pricing and quality strategies as well as on societal welfare, in a market with both horizontally as well as vertically differentiated products. The analysis gives further insight into the effect of the policy under three different market structures: competitive market, local monopolies and exogenous full market coverage. The author finds it difficult to conclude the supremacy of one pricing policy to another in all dimensions when considering pharmaceutical expenditure control. Most importantly, while the relationship between prices, product qualities and market coverage is sensitive to the relationship between the copayment-rate and the reference price level, a multiplicity of outcomes is likely to arise. In addition, the author also finds that even if drug prices are reduced as a result of

the implementation of a reference pricing policy, this can lead to welfare-losses if quality or market coverage vary negatively after the introduction of such a policy. In the set-up of the exogenously covered market, the author proves that reference pricing is nested in the co-payment system, meaning that the equilibria prices and qualities are independent of the introduction of a reference price. In this case, the author concludes that reference price cannot be used as a regulatory instrument for the determination of prices, qualities or for market coverage.

In their analysis of the reference pricing system Brekke et al. (2007) bring an important contribution to the existing theoretical frameworks by including generic as well as therapeutic reference pricing in their analysis. The authors combine all three scenarios – generic, therapeutic and no reference pricing – into a single framework by assuming horizontal as well as vertical product differentiation. The market comprises two horizontally differentiated brand-name drugs; one off-patent and the other still under patent protection. In addition, the off-patent firm faces a vertically differentiated generic competitor in the existing market. The other branded drug will be introduced to the market if the profits are sufficient to cover its entry costs. By comparing the relative effects of both generic and therapeutic reference pricing relative to no reference pricing the authors show that, in the scenario involving competition from another therapeutic class, competition is at its fiercest with lowest equilibria prices for all firms. Impressively, compared to generic reference pricing, therapeutic reference pricing also leads to lower patient health costs, indicating a better alternative from a welfare perspective as well. Conversely, the authors demonstrate that generic reference pricing leads to the highest aggregate mismatch costs for patients relative to the other two reimbursement systems. However, the tailwind of the therapeutic reference price system endures only as long as the market entry costs remain sufficiently small. Whenever the patented drug does not choose to enter the market, both the generic reference pricing as well as the benchmark-case of no reference pricing offer better welfare outcomes since now the former will always lead to highest patient health costs as well as to higher prices.

### 3. Finnish pharmaceutical sector and the reference pricing system

Admittedly, the theoretical foreground for reference pricing schemes has remained on a rather general level and few attempts have been made to apply the frameworks into any single national regulatory environment. In order to apply theory into practice, however, one must first understand the institutional as well as the regulatory environment that may influence the build-up and the interpretation of the theory.

The Finnish pharmaceutical sector is embedded with a few key institutions which have pivotal roles in the organization of the health care sector by the means of determining the conditions to the access to, reimbursement of, and the authorization for firms to sell pharmaceuticals. Furthermore, the laws and decrees stipulating the rules in the industry are of great interest in my analysis. First and foremost, it is stipulated in the Health Insurance Act (1224/2004) that all Finnish residents are entitled to receive reimbursement of necessary expenses incurred in treating an illness. The Social Insurance Institution (Kela) is responsible for enforcing the Act by implementing the ordeal of health insurance. In addition, Kela validates and monitors the compliance of the Act as well as the decrees and regulations issued thereunder.

The Pharmaceutical Pricing Board (HILA), which is directly responsible for the Ministry for Social Affairs and Health, decides on the confirmation of reimbursement status for pharmaceuticals and a reasonable wholesale price without which the reimbursement status cannot be granted. Most importantly, HILA determines the reference price groups, the products included in the groups and the reference price for each quarter of a year (HILA, 2019). A reference price group for medicinal products is formed of reimbursable medicinal products that are included in the sphere of generic substitution and have a sales permit, provided that the reference price group to be formed contains at least one substitutable generic product available on the market (Act 1224/2004). Moreover, the groups consist of medicines which share the same active ingredient, the same strength and same pharmaceutical form, and they must be sold in comparably sized packages. In the Finnish generic substitution system, dispensing pharmacies are obligated to inform the customer about the least expensive substitutable product when purchasing drugs. Nevertheless, customers have the right to choose a more expensive medicine as well. However, if the drug belongs to a valid reference price group, the customer will lose the right to reimbursement for the price-difference exceeding the reference price.

According to the Act 1224/2004 (Amendment 802/2008), a reference price is determined based on the least expensive medicinal product included in the substitution group. By the law, the reference price is calculated by adding 0,50 euros to the taxable price of the least expensive medicine in the substitution group. In effect, the Finnish reference price constitutes a fixed mark-up charged over the cheapest drug. In general, the reimbursement limit of the health insurance provided by Kela is set according to the prevailing reference price for respective reference price groups. However, the prescribing physician can rule out substitution of a drug on medical or therapeutic grounds, in which case the reimbursement will be granted for the full price of the medicine.

#### 4. Theoretical model: Stackelberg duopoly

I will now present the theoretical framework of my study in order to reach a hypothesis of outcomes subject to the reference pricing reform in the Finnish pharmaceutical markets. During the implementation of my quantitative analysis the theoretic application of the Stackelberg model, including the algebraic notation, will follow that of Merino-Castelló (2003) who applies both Stackelberg as well as Bertrand models in the context of a reference pricing reform in the Spanish pharmaceutical market. However, in the context of the Finnish reference price system I will make a slight deviation from Merino-Castelló's mathematical formulation which results in slightly alternating competitive outcomes for generic and branded drug firms. On the one hand, my results support Merino-Castelló's findings for increased market shares for the branded-drug firm, even with a slightly differently defined reference price. On the other hand, including sensitivity analysis of different reimbursement categories of drugs into the model complements Merino-Castelló's research by differentiating the magnitude of the reference price reform according to drugs with different copayment rates.

Similar to Merino-Castelló, the analysis proceeds in two consecutive steps. The first step is to derive and determine the effect of reaching a price and product quality equilibrium in the

Stackelberg model. Subsequently, the Finnish reference price reform will be introduced and implemented into the equations in order to analyze its effect on the model. Additionally, the Stackelberg-game comprises two sub-games. Before the implementation of the pricing reform, the firms will first solve the price-setting game by determining the profit-maximizing product prices. Subsequently, the firms are up to solving the quality game where the profits are made endogenous of the drugs' quality specifications. After the implementation of the reference price system the quality game can be disregarded since the level of product quality has already been decided. As usual, the games are solved with the help of backward induction.

In the course of the analysis, vertical product differentiation is assumed and two participants are present in the game. The market comprises a company producing brand-name drugs and a generic drug company producing drugs with identical therapeutic effect but differentiated perceived quality in contrast to the branded drug. The perceived quality is higher with the branded drug because of higher switching costs for the patient and the prescribing physician (Carroll & Wolfgang, 1991; Mason & Bearden, 1980). The game is played once the patent of the brand-name drug producer has expired. Since the game comprises only two players, it must be accounted for its simplicity and lack of authenticity in depicting the reality of pharmaceutical markets with conventional synthetic drugs, where the expiration of a patent, especially an economically lucrative one, can attract more than just one competitor into the market.

Furthermore, the original innovator company can produce generic copies of its own product, called pseudo-generics, simultaneously while producing and selling its branded drug in order to apply third degree price discrimination and to block its rivals' entry even when independent firms producing true generics face low entry costs (Merino-Castelló, 2003; Kong & Seldon, 2004). However, assuming more reluctant potential competitors due to a higher brand-value of the incumbent firm, and assuming that the brand-name drug company does not indulge in licensing or producing pseudo-generics, uncertainty for entering the market is expected to persist so that the market endures a transition phase of duopolistic competition with only one generic competitor facing the innovator firm.

#### 4.1 Demand in the pharmaceutical market

In order to derive the profit functions of the pharmaceutical firms we need to model the demand for generic and branded drugs. The demand functions are extrapolated from the maximization of consumer utility. The consumption of both generic (  $G$  ) and branded (  $B$  ) drugs is depicted by the same utility function for consumers.

$$U(v, \theta_i) = \begin{cases} v\theta_i - kp_i & \text{if consumer buys one unit} \\ 0 & \text{otherwise} \end{cases} \quad i = B, G \quad (1)$$

The utility  $U(v, \theta_i)$  from consuming one unit of drug, be it generic or branded, is depicted by the surplus gained from the positive difference between the drug's perceived quality (  $\theta_i$  ) and the out-of-pocket cost (  $kp_i$  ) for the patient. The coinsurance rate (  $k$  ) is represented as a percentage share of the drug's retail price (  $p_i$  ) borne by the consumer, whereas the remaining drug cost  $(1 - k)p_i$  is

borne by the public health insurer. The consumers have a choice of consuming either one unit of generic drug, one unit of branded drug or no drug at all.

Consumers' sensitivity to price changes between generic and branded drugs is depicted by the parameter  $\nu$ . The higher values  $\nu$  gets, the lower incentive to change to a cheaper alternative the consumer feels, which leads to more insensitive reactions to price changes. In contrast, with lower values of  $\nu$  the consumer exhibits lower switching costs between the drugs, leading to a higher price sensitivity among consumers. In addition, this parameter represents a uniformly distributed continuum of consumers indexed by their level of price sensitivity on the interval  $\nu = [0,1]$ . Figure 2 depicts the distribution of  $\nu$  and the illustrative relative quantities of drugs demanded by the consumers. Finally, the perceived quality of the drug can be either high ( $\theta_B$ ) or low ( $\theta_G$ ).

While  $U(\nu, \theta_i)$  denotes the utility from drug consumption, consumers are not assumed to face any budget constraints. Consequently, the consumer is not hindered to consume whenever she gains surplus utility from consumption. Furthermore, Merino-Castelló's (2003) notation is followed and it is assumed that whenever consumers are indifferent between buying and not buying a drug, they will buy the drug. Moreover, when consumers are indifferent between buying a brand-name drug and a generic drug, they opt for the brand-name drug.

In effect, we can conclude that consumers buy the generic drug as long as the following criteria are satisfied:

$$\left\{ \begin{array}{l} \nu\theta_G - kp_G > \nu\theta_B - kp_B \rightarrow \nu < \frac{k(p_B - p_G)}{\theta_B - \theta_G} \\ \nu\theta_G - kp_G \geq 0 \rightarrow \nu \geq \frac{kp_G}{\theta_G} \end{array} \right. \quad (2)$$

However, the consumer opts for a branded drug as long as:

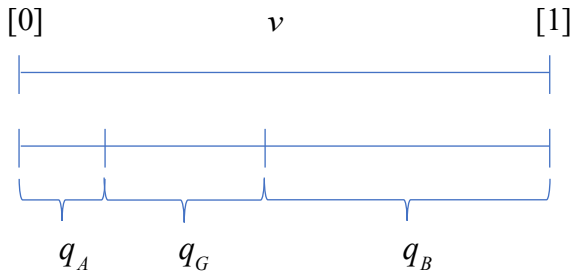
$$\left\{ \begin{array}{l} \nu\theta_B - kp_B \geq \nu\theta_G - kp_G \rightarrow \nu \geq \frac{k(p_B - p_G)}{\theta_B - \theta_G} \\ \nu\theta_B - kp_B \geq 0 \rightarrow \nu \geq \frac{kp_B}{\theta_B} \end{array} \right. \quad (3)$$

Now we can write the demand functions for branded and generic drugs respectively:

$$\left\{ \begin{array}{l} q_B = 1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G} \text{ for branded drugs} \\ q_G = \frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G} \text{ for generic drugs} \end{array} \right. \quad (4)$$

To better illustrate the demand functions we can depict a distribution of the demanded quantities aligned with the values of the parameter  $\nu$  on a line segment.

Figure 2. Distribution of drug demand based on demand elasticity: An illustration



The demand for branded drugs ( $q_B$ ), generic drugs ( $q_G$ ) and the demand for abstaining from buying drugs altogether ( $q_A$ ) is represented as sub-parts of the line segment indicating the continuum of  $\nu$  on the interval  $\nu = [0, 1]$  in Figure 2. Most importantly, we notice that consumers with sufficiently high switching costs, denoted by higher values of  $\nu$ , who are thus exhibiting more inelastic demand for branded drugs due to higher brand loyalty or otherwise higher switching costs, will opt for the branded drug.

Correspondingly, the demand for generic drugs incurs with high enough values of  $\nu$  in order for the consumer to derive any surplus from consumption, but low enough values so that the superior quality of the branded drug does not cause the consumer to opt for the branded drug. Since the demand for non-demand for drugs ( $q_A$ ) is a clumsy expression, a more coherent notation is appraised with total market demand for drugs denoted simply as  $Q = q_B + q_G$ . Thus, we can compare the respective market shares of branded and generic drugs once we have solved their respective quantities demanded.

#### 4.2 Supply in the pharmaceutical market

We can now proceed to address the factors contributing to the supply side of the model. Before setting prices both the generic and branded drug producers decide on the quality  $\theta$  of the drug so that  $1 > \theta_B > 0.5 > \theta_G > 0$ . There is no upper bound to the quality, however, a lower bound is assumed in order for the generic drug to pass the bioequivalence requirement and obtain market authorization.

Furthermore, sufficient promotional expenses are required in order for both the generic and branded drug firms to penetrate the market. In addition, both firms are subject to R&D expenses leading to the launch of their respective product, granted that these are substantially higher for the innovator firm because the generic drug firm can more or less copy the development process of the branded drug once the patent has expired.

The minimum quality requirements for the drug can be interpreted as a *Minimum Quality Standard* (MQS) which is demonstrated to lead to more intense quality differentiation among producers (Ronnen, 1991). In order to meet the MQS each firm incurs a fixed cost of quality improvement (Motta, 1993):

$$C_i = \frac{\theta_i^2}{2} \quad i = B, G \quad (5)$$

Once the firms are ready to decide upon prices, quality improvement costs have already sunk and constant unit production costs are incurred. Without loss of generality these costs are assumed to be zero (Motta, 1993).

### 4.3 Price-setting Game

We can now write the profit functions respectively for the generic and branded drug firm.

$$\begin{cases} \pi_B = p_B \left[ 1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G} \right] \\ \pi_G = p_G \left[ \frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G} \right] \end{cases} \quad (6)$$

Firm G's price-setting problem is to maximize its profit function with respect to its price. Therefore, we proceed by solving the first-order-condition (FOC):

$$\frac{\delta \pi_G}{\delta p_G} = \left[ \frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G} \right] + p_G \left[ \frac{-k}{\theta_B - \theta_G} - \frac{k}{\theta_G} \right] = 0 \quad (7)$$

From the latter, we can now decipher G's *reaction function* that gives the optimal choice for  $p_G$  as a function of  $p_B$ :

$$p_G = \frac{\theta_G}{2\theta_B} p_B \quad (8)$$

Similar to G, firm B's price-setting problem is to maximize its respective profit function with respect to its price, but given G's reaction function. G's reaction function is thus plugged into B's price-setting problem so that the FOC can be set:

$$\frac{\delta \pi_B}{\delta p_B} = \left[ 1 - \frac{kp_B - k \frac{\theta_G}{2\theta_B} p_B}{\theta_B - \theta_G} \right] + p_B \left[ \frac{-k}{\theta_B - \theta_G} + \frac{k \frac{\theta_G}{2\theta_B}}{\theta_B - \theta_G} \right] = 0 \quad (9)$$



Once the latter expression is solved for  $p_B$  we can substitute in order to get  $p_G$ :

$$\begin{cases} p_B = \frac{\theta_B(\theta_B - \theta_G)}{k(2\theta_B - \theta_G)} \\ p_G = \frac{\theta_G(\theta_B - \theta_G)}{2k(2\theta_B - \theta_G)} \end{cases} \quad (10)$$

#### 4.4 Quality Game

When we plug the respective price functions of the generic and branded drug firms into the profit functions we end up with endogenous profit functions comprising the functions of the quality specifications:

$$\begin{cases} \pi_B = \frac{\theta_B(\theta_B - \theta_G)}{2k(2\theta_B - \theta_G)} - \frac{\theta_B^2}{2} \\ \pi_G = \frac{\theta_B\theta_G(\theta_B - \theta_G)}{4k(2\theta_B - \theta_G)^2} - \frac{\theta_G^2}{2} \end{cases} \quad (11)$$

Next, the procedure follows that of the price-setting game where the branded drug firm maximizes its profit function subject to the constraints  $\frac{\delta\pi_G}{\delta\theta_G} = 0$ ,  $1 > k > 0$ ,  $1 > \theta_B > 0.5$  and

$0.5 > \theta_G > 0$ . The constrained optimization problem is solved with *Mathematica* with alternating values for the coinsurance rate  $k$ . According to the Finnish Social Insurance Institution (Kela, 2019) the basic rate of reimbursement for medicines is 40 percent. In addition, Kela defines lower and higher rates of special reimbursement for medicines corresponding to 65 and 100 percent respectively.

The profit functions of the generic and branded drug firms are maximized using Kela's three rates for drug reimbursement in order to address the sensitivity of the model. However, instead of Kela's highest special reimbursement rate, a slightly lower rate is used in order for the equations to perform properly. Using the full reimbursement rate of 100 percent would equal the use of a coinsurance rate of zero percent (1-reimbursement rate) which would lead to undefined algebraic results. Therefore, instead of the full reimbursement rate, a rate of 99 percent is used instead. In addition of satisfying the computational requirements, the lower reimbursement rate also reflects better the reality of cost sharing in the Finnish medical coinsurance policy. In effect, even though Kela pays the full reimbursement of 100 percent for selected prescription drugs, the consumer is still liable to pay a small copayment (Kela, 2019).

$k$	$\theta_B$	$\theta_G$	$\theta_B - \theta_G$	$P_B$	$P_G$	$P_B - P_G$	$\frac{q_B}{Q}$	$\frac{q_G}{Q}$
0.60	0.50	0.10	0.40	0.3704	0.0370	0.3333	64 %	36 %
0.35	0.7132	0.1682	0.5451	0.8827	0.1041	0.7787	64 %	36 %
0.01	0.7689	0.50	0.2689	19.9231	6.4777	13.4454	57 %	43 %

Table 1. Results comparison

In Table 1 I have tabulated the results of the price and quality equilibria as well as the respective market shares of the generic and branded drug firms in the three differing reimbursement scenarios. Among other things, we notice that in the basic reimbursement class of medicines (top row) price competition between the drug firms seems to be more intense compared to the other two scenarios. Furthermore, the market structure is identical in the two lowest reimbursement categories with respect to the market shares, whereas in the therapeutic market with the lowest co-payment rate for the patient, the generic producer is able to gain slightly more market share compared to the other scenarios. Moreover, prices for both generic and branded drug firms are positively related to the reimbursement rate as the public health insurer backs up consumer demand by paying a larger proportion of the patient's drug bill. Since prices become a less important factor contributing to the purchasing decisions of consumers, quality-differentiation intensifies since the generic firm attempts to appeal to consumers with better quality.

#### 4.5 Reference-price reform

It is evident from the Health Insurance Act (Amendment 802/2008) that the reference price for reimbursable pharmaceuticals in Finland is determined once the Pharmaceutical Pricing Board (HILA) has received enough price notifications from the members of a reference price group. After HILA has received and processed the price information provided by the market authorization holders a reference price is fixed for a limited time period. Moreover, the reference price is determined by adding a fixed mark-up to the cheapest drug in the reference price group. In contrast to Merino-Castelló (2003), who determines the reference price as a linear function of both branded and generic drug prices, I model the reference price so that it reflects more accurately pharmaceutical price regulation in Finland.

Since the pharmaceutical market in the Stackelberg model comprises only two players, the reference price ( $p_R$ ) is modeled as a sum of the generic drug company's *ex-post* drug price ( $p_G$ ) and a constant  $\alpha$  representing the intensity of the reference price reform.

$$p_R = p_G + \alpha \quad (12)$$

If the price set by the branded-drug firm is within modest reach, represented by the constant  $\alpha$ , of that of the generic firm's price, the innovator drug company can still receive reimbursement for its total drug price. However, if the price differential between the generic and branded-drug firm is exceeded by more than the amount of  $\alpha$ , the differential between the branded-drug price and the reference price is excluded from the reimbursement system and the differential is wholly paid by the consumer.

The maximum price differential between the drug firms entitled to the full reimbursement status is determined *ex-ante* with a non-conservative value so that the magnitude of the pricing reform is not left ambiguous. It is determined as roughly 10 percent of the generic drug price in the general reimbursement class before the reference price reform has taken place. Consequently, we define  $\alpha = 0.0037$ .

The consumers now buy the branded drug as long as:

$$\left\{ \begin{array}{l} v\theta_B - k(p_G + \alpha) - (p_B - p_G - \alpha) \geq v\theta_G - kp_G \rightarrow v \geq \frac{(k-1)\alpha + p_B - p_G}{\theta_B - \theta_G} \\ v\theta_B - k(p_G + \alpha) - (p_B - p_G - \alpha) \geq 0 \rightarrow v \geq \frac{(k-1)(\alpha + p_G) + p_B}{\theta_B} \end{array} \right. \quad (13)$$

In contrast, for the consumers who opt for the generic drug the following criteria must hold true:

$$\left\{ \begin{array}{l} v\theta_G - kp_G > v\theta_B - k(p_G + \alpha) - (p_B - p_G - \alpha) \rightarrow v < \frac{(k-1)\alpha + p_B - p_G}{\theta_B - \theta_G} \\ v\theta_G - kp_G \geq 0 \rightarrow v \geq \frac{kp_G}{\theta_G} \end{array} \right. \quad (14)$$

The reference price indicates an additional but avoidable copayment for the branded product but no additional copayment for the generic product (Merino-Castelló, 2003). Accordingly, the demand functions become slightly alternated with the introduction of a reference price:

$$\left\{ \begin{array}{l} q_B = 1 - \frac{(k-1)\alpha + p_B - p_G}{\theta_B - \theta_G} \text{ for branded drugs} \\ q_G = \frac{(k-1)\alpha + p_B - p_G}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G} \text{ for generic drugs} \end{array} \right. \quad (15)$$

At this stage of the game, the quality game can be disregarded since the costs for quality improvements have already sunk. Consequently, by solving the price-setting game we have reached the ultimate equilibria of the game. By following the same logic as in the price-setting game previously, we can solve the equilibria prices:

$$\left\{ \begin{array}{l} p_B = -\frac{1}{2}(k-1)\alpha + \frac{(\theta_B - \theta_G)[k(\theta_B - \theta_G) + \theta_G]}{2k(\theta_B - \theta_G) + \theta_G} \\ p_G = \frac{1}{4}\theta_G \left[ \frac{(k-1)\alpha}{k(\theta_B - \theta_G) + \theta_G} + \frac{2(\theta_B - \theta_G)}{2k(\theta_B - \theta_G) + \theta_G} \right] \end{array} \right. \quad (16)$$

Table 2 details the descriptive results of the reference price reform with different reimbursement levels. More concisely, the results indicate the effect of setting a maximum reimbursement limit for the public health insurer on market equilibria between the generic and branded-drug firm.

Since the optimal quality specifications have already been chosen for both firms, the introduction of the pricing reform doesn't allow for further modifications on product quality. Therefore, the effect of the reference price will be solely absorbed by price changes, leading to further changes in consumer demand and market shares.

<i>RP reform</i>	$k$	$\theta_B$	$\theta_G$	$\theta_B - \theta_G$	$P_B$	$P_G$	$P_B - P_G$	$\frac{q_B}{Q}$	$\frac{q_G}{Q}$
Before	0.60	0.50	0.10	0.40	0.3704	0.0370	0.3333	64 %	36 %
After	0.60	0.50	0.10	0.40	0.2352	0.0344	0.2008	85 %	15 %
Before	0.35	0.7132	0.1682	0.5451	0.8827	0.1041	0.7787	64 %	36 %
After	0.35	0.7132	0.1682	0.5451	0.3571	0.0831	0.2740	75 %	25 %
Before	0.01	0.7689	0.50	0.2689	19.9231	6.4777	13.4454	57 %	43 %
After	0.01	0.7689	0.50	0.2689	0.2693	0.1321	0.1372	0 %	100 %

Table 2. Effects of the pricing reform

First of all, the implementation of the pricing reform causes price reduction for both firms in all reimbursement categories. More importantly, the innovator firm absorbs the most drastic price drops. While a positive relationship between the reimbursement rate and drug prices can be observed for both firms, the reimbursement rate seems to be also positively related to the intensity of the pricing reform in terms of its effect on drug prices and on the severity of price competition between the manufacturers. This makes intuitive sense when we remember that in the highest reimbursement class, the patient faces the highest marginal cost, compared to drugs in lower reimbursement classes, for buying a drug priced above the reference price, after the pricing reform has been set up. Moreover, after the reference price reform, the generic competitor has a paramount incentive to lower its prices in order for it to capture the demand from the branded-drug firm. As a consequence of the definition of the reference price, the actions of the generic firm directly influence the level of the reference price. However, the branded-drug firm can't independently affect the reference price, and it must follow the actions taken by the generic firm instead. This gives a direct advantage for the generic firm as its price will always be reimbursed.

In effect, the branded-drug firm finds itself in a desperate situation after it loses the advantage of charging higher prices to compensate for higher development costs in order to keep up with changes in the consumer demand. In the scenario with the highest reimbursement class, and with the highest initial sunk costs for quality-improvements, this can be seen clearest: after the implementation of the pricing reform the branded-drug firm can't make a positive return on its investment and the generic firm ends up capturing the whole market. However, in the two lower reimbursement categories for drugs the situation is different. There the originator-drug firm can still recoup its sunk investments, and instead of charging higher prices it sells greater quantities in order to compensate for the decline of profits. I thus find evidence in support of Merino-Castelló's (2003) findings that the implementation of a reference price system can lead to increased market shares for the branded-drug firm.

## 5. Results and discussion

Applying Merino-Castelló's (2003) theoretical framework of a Stackelberg duopoly where both the generic and the branded-drug firm face consumer demand from a heterogeneous pool of patients allows me to formulate some key hypotheses about the competitive outcomes in the Finnish pharmaceutical market. More concisely, the model lets me derive hypotheses about the effect of the reference pricing reform, so as to validate its desired objectives. Furthermore, in order to test the credibility of the model, the hypotheses derived thereof will be assessed in relation to a case study conducted by Koskinen et al. (2014) who perform an investigation of the impact of reference pricing and extension of generic substitution on the daily cost of antipsychotic medication in Finland. Finally, the limitations of the model will be pondered in conjunction with the case study.

### 5.1 Hypotheses based on the Stackelberg model

Perhaps the most obvious effect of the reference price reform seems to be the price-reductions of both branded as well as generic pharmaceuticals. Furthermore, while the generic producer reduces its prices only modestly, the innovator drug firm goes through a more drastic cut in its prices in order to preserve the demand for its products. Consequently, I can derive my first hypotheses:

**Hypothesis 1a:** The implementation of the reference pricing reform leads to reduced prices for both generic and branded-drug firms.

**Hypothesis 1b:** The price-reductions associated to the implementation of the pricing reform will be more severe for the branded-drug firm than for the generic firm.

Additionally, the model lets me perform sensitivity analysis from the impact of the pricing reform on the prices of medicines belonging to different reimbursement categories. As we witnessed from the Stackelberg model, the reimbursement rate is positively related to the intensity of the pricing reform in terms of its effect on price competition. Furthermore, a positive relation also exists between the reimbursement rate and the severity of price reductions undertaken as a consequence of the pricing reform. Accordingly, I can state my second hypothesis:

**Hypothesis 2:** A positive relation exists between the drug reimbursement rate and the magnitude of the effect of the reference pricing reform on drug prices, so that the most drastic price-reductions will occur in the lowest copayment-category of drugs after the reform has been put into effect.

### 5.2 Case study: The impact of reference pricing and extension of generic substitution on the daily cost of antipsychotic medication in Finland

To weigh the credibility of my hypotheses, the findings of the empirical study conducted by Koskinen et al. (2014) will be subsequently disseminated. In their retrospective study of the levels and trends in the cost of one day treatment of selected antipsychotic drugs, the authors use a segmented linear regression analysis of interrupted time series with data provided by Kela for the

years between 2006 and 2010. Their objective is to assess the impact of reference pricing and extension of generic substitution on the daily cost of antipsychotic drugs in Finland during the first year after its launch.

While antipsychotic drugs are primarily indicated for the treatment of psychotic disorders, the drugs have been among the fastest-growing therapeutic classes in Finland in the past decades, and the growth has been mostly explained by the average cost per one day of treatment (Koskinen et al., 2009). The authors (Koskinen et al., 2014) have included clozapine, olanzapine, quetiapine and risperidone to their study as these active ingredients represent the most commonly used antipsychotics in Finland. In terms of their reimbursement status, antipsychotics are included in the highest reimbursement category (100% plus a fixed co-payment of €3.00 per purchase) when used in the treatment of severe psychotic and other severe mental disorders. The lower reimbursement group had a 42% rate of reimbursement with zero fixed co-payment at the time of the study.

While the reference price system was adopted in Finland in April of 2009, during the exact same time it was also decided that pharmaceuticals protected by analogous process patents would be included in the sphere of generic substitution. Whereas clozapine and risperidone were included in generic substitution already before reference pricing was adopted, olanzapine and quetiapine - having both been protected by analogy process patents - were included in generic substitution and reference pricing at the same time. Therefore, the estimation of the effect of reference pricing may already be subject to altering justifications between the antipsychotics.

Most importantly, the authors (Koskinen et al., 2014) conclude that the implementation of reference pricing was associated with a substantial decrease in the daily cost of all four antipsychotics, thus substantiating my hypothesis for price-reductions of pharmaceuticals in the aftermath of the pricing reform. However, while the authors have studied both the effects of generic substitution as well as reference pricing, they are able to conclude that the additional cost savings from reference pricing, following the adoption of generic substitution, are comparatively low.

While the general trend of declining prices was shared between all four antipsychotics as a result of reference pricing, the intensity of the impact of the reform varied between active substances. For instance, while the vast majority of the purchases made for olanzapine drugs were reimbursed according to the highest reimbursement category, the authors speculate that due to a higher opportunity cost for buying an olanzapine drug - had it been priced above the prevailing reference price – compared to quetiapine which was also simultaneously included both to the generic substitution as well as the reference pricing system, the observed cost-reductions for olanzapine were higher as a result of the reform. Should this be the actual reason explaining the different intensities observed of the effect of the reference pricing reform between the two active substances, this would be in favor of my second hypothesis.

However, in addition to the higher opportunity cost being a justification for the more intense price-reductions observed, a couple of other reasons are also validly discussed by the authors. For example, even though higher price-reductions would occur in higher reimbursement categories for drugs as a consequence of the pricing reform, the ultimate reason for this phenomenon could stem from a selection bias rather than a higher opportunity cost. Indeed, as the higher special

refund category can be interpreted as a proxy for illness severity, it is possible that the patients buying olanzapine have more financially constricted resources which might be influenced by the sheer severity of the condition (Koskinen et al., 2014). Consequently, this could influence manufacturers' pricing decisions for the respective drugs. Furthermore, as the production volumes were greater for olanzapine compared to clozapine, which was already included in generic substitution before the implementation of the reference pricing system, olanzapine manufacturers were probably more incentivized to take part in a price competition in the first place, which could in part explain the more severe price-reductions (Koskinen et al., 2014).

Even though my application of Merino-Castelló's (2003) model is sufficient to estimate the direction of the effect of the reference pricing reform, based on the case study by Koskinen et al. (2014) it is evident that the model certainly lacks robustness as it is not able to accommodate the multiplicity of potential causes for the effects of the pricing reform. Furthermore, the model lacks scope since it can only cope with a duopolistic market where the branded-drug firm's patent has already expired, and where pseudo-generics or licensed products are not sold.

Beyond the implications of the case study, the Stackelberg model rests on non-trivial assumptions made about the demand-side as well as the supply-side of pharmaceuticals. For example, the pool of potential patients who will buy a drug is assumed to be uniformly distributed based on the patients' sensitivity to price-changes. Essentially, this assumption makes the presupposition that no consumer is alike and that every type of consumer is represented in the pool at all times. Since this is not by any means an obvious statement, the model warrants alternative views about differing demand structures in the pharmaceutical market. In addition, while the model takes a stance on perceived quality of the drug production, it offers very little insight on the actual quality of pharmaceuticals or the manufacturers' incentives to invest in innovative drugs with better therapeutic value. Hence, the model fails to disentangle the effects on societal welfare.

## 6. Conclusion

This paper evaluates the impact of the reference price reform on pharmaceutical market equilibria in Finland. The market for pharmaceuticals is crippled by market failures, prompting actions in the form of extensive regulation used by national authorities in order to promote rational drug consumption. Price regulation in the European Union has proved effective in containing pharmaceutical prices, although concerns linger about the anticompetitive effects of the administered regulatory measures (Moreno-Torres et al., 2009; Puig-Junoy, 2010). Setting a reimbursement cap, i.e. a reference price, on publicly reimbursable pharmaceuticals is an example of an effective regulatory measure used to contain both public and private drug spending.

The application of Merino-Castelló's (2003) theoretical model in the context of a reference price reform introduced in Finland enables the determination of the effects of the pricing reform on pharmaceutical prices and market shares for generic and branded drugs respectively. Moreover, the model provides insight on the role of different reimbursement categories of drugs in the evaluation of the magnitude of the regulatory impact.

Using Merino-Castelló's (2003) model with vertically differentiated products and uniformly distributed consumers based on their demand elasticity, I evaluate the marginal effect of the reference price reform conducted in Finland compared to a copayment-regime where consumers only pay a proportion of their drug(s) according to the reimbursement category covering the drug(s). The introduction of a reference price entails an additional but avoidable surcharge for pharmaceuticals priced above the reference price. Effectively, the drug demand becomes alternated and consumers become more incentivized to switch to buying the cheapest drug. By applying Merino-Castelló's model where a generic and a branded-drug firm compete *à la Stackelberg* into the Finnish regulatory environment, I observe a multitude of results.

First, the implementation of a reference price is capable of reducing pharmaceutical prices across the board, with the most drastic price-reductions occurring for the branded drugs. This result is also in line with prevailing research (Puig-Junoy, 2010). Second, the implementation of the reform indicates increasing market shares for the branded-drug firm and decreasing market shares for the generic firm, at least in the general reimbursement category and lower special reimbursement category of drugs. While empirical research on changes in market shares of pharmaceuticals due to the reference pricing reform remains scarce, my results nevertheless support those found in earlier theoretical research (Merino-Castello, 2003). Third, performing sensitivity analysis on the Stackelberg model reveals that whereas drugs belonging to a reimbursement category with lower out-of-pocket copayment costs for the patient are priced higher across the board, drugs with lower copayments for consumers are also associated with a more severe negative impact, after the reference price reform, on pharmaceutical prices. Evidence in support of this phenomenon is provided by Koskinen et al. (2014) in their case study about the impact of reference pricing and extension of generic substitution on the daily cost of antipsychotic drugs in Finland.

Finally, while the results suggest that the introduction of the Finnish reference price system successfully contains pharmaceutical price levels by stimulating more active price competition between the pharmaceuticals, the sign of an increased price competition amongst the existing manufacturers says little about the effects on the overall supply of pharmaceuticals. Moreover, since lower prices can deter further competition, the reference price system can pose a constraint on drug innovation, resulting in lower societal welfare.



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